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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,608	11/01/2001	Gabor T. Bartha	IN-0040 US	5161

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EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/08/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/003,608

Applicant(s)

BARTHA ET AL.

Examiner

Carolyn L Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 5,6 and 15-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-14 is/are rejected.
- 7) ☒ Claim(s) 3, 8, and 12 is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Applicants' election without traverse of Group I (claims 1-4 and 7-14) in Paper No. 8, filed 6/20/03, is acknowledged. Claims 5-6 and 15-22 are withdrawn from consideration as being drawn to non-elected Groups.

Claims herein under examination are 1-4 and 7-14.

Claim Objections

Claims 3, 8, and 12 are objected to because of the following minor informality:
"differential" on line 3, 4, and 4, respectively, should end in "ly" to be in proper adverb form.
Appropriate correction is requested.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-4 and 7-14 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4 and 11-18 of copending Application No. 10/235994. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. As written, the claims appear to lack any physical result performed outside of a computer.

As stated in MPEP § 2106, (IV)(2)(b), to be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan (discussed in MPEP § 2106 (IV)(2)(b)(i)), or (B) be limited to a practical application within the technological arts (discussed in MPEP § 2106 (IV)(2)(b)(ii)).

As stated in MPEP § 2106 (IV)(2)(b)(i), the independent physical acts may be post- or pre-computer processing activity as described below:

A process is statutory if it requires physical acts to be performed outside the computer independent of and following the steps to be performed by a programmed computer, where those acts involve the manipulation of tangible physical objects and result in the object having a different physical attribute or structure. *Diamond v. Diehr*, 450 U.S. at 187, 209 USPQ at 8. Thus, if a process claim includes one or more post-computer process steps that result in a physical transformation outside the computer (beyond merely conveying the direct result of the computer operation), the claim is clearly statutory.

Another statutory process is one that requires the measurements of physical objects or activities to be transformed outside of the computer into computer data (In re Gelnovatch, 595 F.2d 32, 41 n.7, 201 USPQ 136, 145 n.7 (CCPA 1979) (data-gathering step did not measure physical phenomenon); *Arrhythmia*, 958 F.2d at 1056, 22 USPQ2d at 1036), where the data comprises signals corresponding to physical objects or activities external to the computer system, and where the process causes a physical transformation of the signals which are intangible representations of the physical

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objects or activities. Schrader, 22 F.3d at 294, 30 USPQ2d at 1459 citing with approval Arrhythmia, 958 F.2d at 1058-59, 22 USPQ2d at 1037-38; Abele, 684 F.2d at 909, 214 USPQ at 688; In re Taner, 681 F.2d 787, 790, 214 USPQ 678, 681 (CCPA 1982).

As stated in MPEP § 2106 (IV)(2)(b)(ii), the computer-related process may be limited to a practical application in the technological arts as described below:

There is always some form of physical transformation within a computer because a computer acts on signals and transforms them during its operation and changes the state of its components during the execution of a process. Even though such a physical transformation occurs within a computer, such activity is not determinative of whether the process is statutory because such transformation alone does not distinguish a statutory computer process from a nonstatutory computer process. What is determinative is not how the computer performs the process, but what the computer does to achieve a practical application. See Arrhythmia, 958 F.2d at 1057, 22 USPQ2d at 1036.

Claims 7-14 do not fulfill either of these statutory requirements and are therefore rejected under 35 U.S.C. 101 because the claim is directed to non-statutory subject matter.

Claims 7-14 are also rejected under 35 U.S.C. 101 because the claimed invention is directed to the non-statutory subject matter of merely performing mathematical computations.

MPEP § 2106, (IV)(1) states the following:

If the “acts” of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not being applied to appropriate subject matter. Schrader, 22 F.3d at 294-95, 30 USPQ2d at 1458-59. Thus, a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

In practical terms, claims define nonstatutory processes if they:

- consist solely of mathematical operations without some claimed practical application (i.e., executing a “mathematical algorithm”); or
- simply manipulate abstract ideas, e.g., a bid (Schrader, 22 F.3d at 293-94, 30 USPQ2d at 1458-59) or a bubble hierarchy (Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759), without some claimed practical application.

MPEP § 2106, (IV)(2)(b)(ii) states the following:

A process that merely manipulates an abstract idea or performs a purely mathematical algorithm is non-statutory despite the fact that it might inherently have some usefulness.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 7-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 1 (line 5), 7 (line 7), and 11 (line 7) recite the phrase "said disease-specific genes with the expression patterns of the genes of unknown function" which is unclear in that it only refers to multiple genes, whereas the original mention of expression patterns in step b) includes one or more genes. It is unclear if Applicants have intentionally eliminated expression patterns from one gene in comparison step c). Clarification of the metes and bounds of this issue is requested. Claims 2-4, 8-10, and 12-14 are also rejected due to their direct or indirect dependence from claims 1, 7, and 11.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. (e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (Genome Research, Vol. 9, 1998, pages 1198-1203) in view of Gupta et al. (P/N 6,424,921) and Friedman et al. (RECOM 2000, pp, 127-135).

Walker et al. describe a method of comparing expression patterns of disease-specific genes with previously unidentified genes that have similar expression patterns (p. 1198, abstract). Walker et al. examined the expression of 40,000 genes and identified a subset of several hundred previously unidentified genes that are associated with various diseases (p. 1198, abstract). Walker et al. describe generating an expression data vector for each expressed gene by categorizing whether each gene is differentially expressed or not differentially expressed (p.

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1200, col. 2, third paragraph; p. 1201, col. 1, second paragraph; and Table 4). Walker et al. describe analyzing vectors of two or more expressed genes to determine a co-differential expression probability (p. 1199, col. 1, second paragraph and p. 1201, col. 1, third paragraph). Walker et al. describe determining whether the probability for the multiple genes is less than a specified probability threshold (p. 1201, col. 2, paragraphs 1-3) as stated in claim 3. Walker et al. do not teach the steps of receiving a plurality of dual channel DNA microarray images, receiving a plurality of single channel DNA microarray images.

Gupta et al. describe analyzing gene expression patterns via hybridization and receiving a plurality of single channel DNA images (Figure 4, #414; col. 1, lines 29-34 and 54-59; col. 2, lines 44-65) and determining a ratio between the images to yield a plurality of dual channel DNA microarray images (col. 2, lines 5-14, 25-39; and Figures 1-4) as stated in claims 2, 10, and 14. Gupta et al. describe hybridization of two different colored fluorescent dyes on a microarray which is then measured via a laser scanner (col. 1, line 54 to col. 2, line 5). Gupta et al. describe averaging hybridization arrays from multiple user selected dual channel hybridization arrays (abstract). Gupta et al. describe a query process with databases (Figure 1, #101 and 102) that support various types of querying of hybridized microarrays, such as BLASTA, BLAST2, FASTA and so forth (col. 6, lines 54-60 and 66-67) which is reasonably interpreted to include translating genes to generate polypeptides which is performed in various BLAST searches, such as blastx and tblastx (<http://www.ncbi.nlm.nih.gov/BLAST/>). Gupta et al. describe a using a computer system including computer program for this analysis with a software product stored on a computer readable medium (col. 3, line 49 to col. 4, line 18) as stated in claims 7-10. Gupta et al. describe using an interface for the user to select processes for execution (col. 4, lines 19-30)

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which is reasonably interpreted as a computing device that is configured to store program instructions temporarily as stated in claims 10-14.

Friedman et al. describe the use of DNA hybridization arrays and using found measurements to discover gene/protein interactions in the gene expression data analysis (abstract). Friedman et al. describe the use of Bayesian networks to describe interactions between genes using algorithms (abstract, third paragraph). Friedman et al. describe using searches such as Psi-Blast, Pfam, and Protomap when ORFs are unknown to reveal firm homologies to proteins functionally related to another gene (p. 133, col. 1, fourth paragraph) which is reasonably interpreted as translating genes of unknown function to generate polypeptides as stated in claims 4, 9, and 13.

Friedman et al. state a major challenge exists to discover gene/protein interactions and key biological features of cellular systems from multiple expression measurements of DNA hybridization array analysis (abstract, first and second paragraphs). Friedman et al. discuss search methodologies for unknown ORFs during gene expression analysis (p. 133, col. 1, fourth paragraph). Walker et al. also discuss predicting gene function by genome-scale expression analysis (title), including studying 40,000 genes for novel, unknown, genes whose expression patterns mimic those of known disease-associated genes (abstract). Gupta et al. also discuss analyzing arrays (abstract), including the use of composite hybridization arrays which are formed from a user selected set of hybridization arrays which are analyzed and placed in a database that can then be available for searching, analysis, and other data processing with other types of hybridization arrays (abstract). Gupta et al. state this allows multiple different nucleotide arrays to be efficiently consolidated and analyzed (abstract). Gupta et al. state using microarrays with

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10,000 array locations. A person of ordinary skill in the art would have been motivated to employ the efficient methods, computer program product, and device (as stated by Gupta et al.) in predicting function of unknown genes (as stated by Walker et al. and Friedman et al.), because this would allow for more efficient discovery of gene/protein interactions and key biological features (as stated by Friedman et al.) in the search of differentially expressed genes as pharmaceutical intervention candidates (as stated by Walker et al., p. 1198, col. 1, first paragraph). One would reasonably have expected success as Gupta et al. provided a way of correctly averaging the relative abundances from multiple hybridized microarrays (col. 2, lines 44-45) and Friedman et al. provided search methods involving unknown ORFs (p. 133, col. 1, fourth paragraph) allowing for detection of mimicking expression patterns as stated by Walker et al. (abstract).

Thus, Walker et al., in view of Gupta et al. and Friedman et al., motivate claims 1-4 and 7-14.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

August 27, 2003


ARDIN H. MARSCHEL
PRIMARY EXAMINER